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| 10/797,948 | 03/11/2004 | Stephen T. Anderson | 20030087.ORI | 4842 |

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| ART UNIT | PAPER NUMBER |
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3766

DATE MAILED: 08/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | | |
|------------------------------|------------------------|--|---------------------|--|
| Office Action Summary | Application No. | | Applicant(s) | |
| | 10/797,948 | | ANDERSON ET AL. | |
| | Examiner | | Art Unit | |
| | Eugene T. Wu | | 3766 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 and 14-18 is/are rejected.
- 7) ☒ Claim(s) 12 and 13 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 March 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Drawings

1. The drawings are objected to as failing to comply with 37 CFR 1.84(l) because they are not adequately well-defined to permit satisfactory reproduction characteristics:

See figures 2, 3, and 9.

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description:

Figure 5: 90 printing final report, referenced on Page 14, line 19; 92 selecting AV delay, referenced on Page 15, line 3; 96 selecting VV delay, referenced on Page 15, line 12.

Figure 6: 82 stored into tables, referenced on Page 12, line 12; 84 Stored Data Sets, referenced on Page 15, line 8.

3. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference characters "102" and "104" in Figure 7 have been used to designate multiple columns of data.

4. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description:

Figure 8: Columns and rows are unlabeled, referenced on Page 13, lines 8-30.

5. The drawings are objected to because there are typographical errors:

Figure 2: 6 should be 46 as referenced on Page 9, line 21.

6. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "a common set of equipment" in claims 15 and 16 and "using an end-tidal CO₂ analyzer" in claim 18 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Art Unit: 3766

7. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

8. The abstract of the disclosure is objected to because the title is misspelled as "Abstact...". Correction is required. See MPEP § 608.01(b).

9. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required:

- a. Claims 15 and 16: Line 1, "a common set of equipment" lacks sufficient antecedent basis in the specification.
- b. Claim 18: Line 2, "end-tidal CO₂ analyzer" lacks sufficient antecedent basis in the specification.

Art Unit: 3766

Appropriate correction is required.

Claim Objections

10. Claims 2-6, and 9-14 are objected to because they repeatedly fail to provide proper antecedent basis for the claimed subject matter. For example:

- a. Claim 2: Line 2, "the oxygen pulse" should be "an oxygen pulse".
- b. Claim 7: Line 2, "them" lacks sufficient antecedent basis.
- c. Claim 9: Lines 1-2, "said non-invasive cardiopulmonary exercise variables", and Line 3, "them", lacks sufficient antecedent basis.
- d. Claim 12: Lines 1-2, "selection of the optimal combination of AV and VV delay values" lacks sufficient antecedent basis. Further, multiple references to steps 9(b,c...) lack antecedent basis.
- e. Claim 14: Line 1, "variables" lacks sufficient antecedent basis.

Applicant's cooperation is requested in identifying and correcting the numerous errors in the claims. Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 14-16, and 18 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claim 14 appears to be a dependent claim but it is unclear what claim it depends on.

Art Unit: 3766

5. Claims 15 and 16 recite the limitation "a common set of equipment" in line 1, but the disclosure fails to further specify a definition. Thus, it is unclear what the Applicant is trying to claim.

6. Claim 18 recites the limitation "end-tidal CO₂ analyzer" in line 2, but the disclosure fails to further specify a definition. Thus, it is unclear what the Applicant is trying to claim.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-8, 14, 15 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Binder (US 6,174,289). For the purpose of examination, claim 14 is considered dependent on claim 1. The phrase in claim 7, "to guide in the placement..." is considered a statement of intended use. Claim 8 is considered a statement of intended use. The phrase "for the purposes of lead placement..." in claim 14 is considered a statement of intended use. The phrase in claim 15, "to optimize all phases of cardiac resynchronization therapy..." is considered a statement of intended use.

9. Binder discloses the invention substantially as claimed, including non-invasively measuring hemodynamic and pulmonary performance in terms of data indicative of a forward pump function (Col. 2, lines 39-67; Col. 3, lines 1-10, 39-57; Col. 14, lines 32-67; Col. 15, lines 1-57; Col. 16, lines 7-32; Col. 18, lines 63-67; Figures 1-5). Binder discloses calculating stroke volume by "estimating cardiac output in liters/min from VO₂ based on standard published equations, then dividing the cardiac output by the patient's heart rate",

Art Unit: 3766

which is considered equivalent to using an oxygen pulse to derive forward pump function (Col. 18, lines 63-67; Col. 19, line 1). Binder discloses using a ventilatory equivalent for CO₂ to derive hemodynamic and pulmonary performance (Col. 19, lines 29-67; Col. 20, lines 1-5). Binder further discloses utilizing a ventilatory efficiency slope (Col. 19, lines 32-37). Binder further discloses displaying cardiopulmonary variables and utilizing them (Col. 3, lines 48-51; Col. 16, lines 1-67; Col. 17, lines 1-67, Col. 18, lines 1-63). Binder further discloses measuring variables under steady-state conditions (Col. 1, lines 19-28; Col. 16, lines 1-14). Binder further discloses utilizing a common set of equipment (Col. 2, lines 39-58; Figures 1-5). Binder further discloses the use of a carbon dioxide analyzer, which is considered equivalent to Applicant's end-tidal CO₂ analyzer (Col. 3, lines 62-67).

10. Claims 1-8, 14, 15, and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Anderson et al. (US 4,463,764). For the purpose of examination, claim 14 is considered dependent on claim 1. The phrase in claim 7, "to guide in the placement..." is considered a statement of intended use. Claim 8 is considered a statement of intended use. The phrase "for the purposes of lead placement..." in claim 14 is considered a statement of intended use. The phrase in claim 15, "to optimize all phases of cardiac resynchronization therapy..." is considered a statement of intended use.

11. Anderson et al. discloses the invention substantially as claimed, including non-invasively measuring hemodynamic and pulmonary in terms of data indicative of a forward pump function (Col. 1, lines 57-67; Col. 2, lines 1-38, 46-67; Col. 3, lines 57-68; Col. 4, lines 27-67; Figure 1, 2). Anderson discloses the use of an oxygen pulse to derive hemodynamic and pulmonary performance (Col. 3, line 64; Col. 14, line 33; Col. 15, line 17; Figure 6). Anderson discloses the use of a ventilatory equivalent for CO₂ to derive hemodynamic and pulmonary performance (Col. 3, line 64; Col. 14, line 34; Col. 15, line 18; Figure 6).

Art Unit: 3766

Anderson further discloses utilizing an end tidal CO₂ (Col. 3, line 62; Col. 14, line 43; Col. 15, line 25; Figure 6). Anderson further discloses displaying cardiopulmonary variables and utilizing them (Col. 1, lines 58-68; Col. 2, lines 1-37; Figures 1, 2, 6). Anderson further discloses measuring variables under a rest condition, which is considered to be equivalent to Applicant's steady-state conditions (Col. 1, 58-67; Col. 2, lines 1-4). Anderson further discloses utilizing a common set of equipment (Col. 1, lines 57-67; Col. 2, lines 1-37; Figures 1, 2). Anderson further discloses the use of a carbon dioxide analyzer, which is considered equivalent to Applicant's end-tidal CO₂ analyzer (Col. 2, line 12).

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. Claims 9-11, 16, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Binder (US 6,174,289) as applied to claim 6 above and further in view of Tockman et al. (US 5,540,727). The phrases "to assist a physician..." in claim 11 and "to optimize all phases..." in claim 16 are considered statements of intended use. Further, claim 17 is regarded as a statement of intended use.

14. Binder discloses the invention substantially as claimed, as described above. Binder further discloses acquiring and displaying cardiopulmonary variables during exercise (Col. 3, lines 48-51; Col. 16, lines 1-67; Col. 17, lines 1-67, Col. 18, lines 1-63). Binder further discloses storing the variables (Col. 4, lines 42-43; Col. 17, lines 42-46; Col. 18, lines 47-54). Binder does not show associating each set with a unique value of AV or VV delay, where the

Art Unit: 3766

AV and VV delay values are defined in a boundary conditions table particular to a pacemaker manufacturer. However, Tockman teaches associating unique values of AV or VV delay with cardiopulmonary variables for the purpose of optimizing pacing parameters in a pacemaker (Col. 4, lines 61-67; Col. 5, lines 1-7; Col. 6, lines 7-12, 33-64). Tockman further teaches having a cardiologist set the cardiac cycle pacing parameters for the pacemaker, which is considered equivalent to Applicant's use of a boundary conditions table, for the purpose of maintaining safe operating parameters for the patient (Col. 3, lines 62-65). Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to modify the method of Binder to associate each cardiopulmonary data set with a unique value of AV or VV delay, where the AV and VV delay values are defined in a boundary conditions table, in order to optimize the pacing parameters in a pacemaker for patient health and safety.

15. Claims 9-11, 16, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al. (US 4,463,764) as applied to claim 6 above and further in view of Tockman et al. (US 5,540,727). The phrases "to assist a physician..." in claim 11 and "to optimize all phases..." in claim 16 are considered statements of intended use. Further, claim 17 is regarded as a statement of intended use.

16. Anderson discloses the invention substantially as claimed, as described above. Anderson further discloses acquiring and displaying cardiopulmonary variables during exercise (Col. 1, lines 58-63; Col. 2, lines 10-37; Figures 1, 2, 6). Anderson further discloses storing the variables (Col. 2, lines 14-29; Col. 14, lines 14-67; Col. 15, lines 1-67; Figure 2). Anderson does not show associating each set with a unique value of AV or VV delay, where the AV and VV delay values are defined in a boundary conditions table particular to a pacemaker manufacturer. However, Tockman teaches associating unique values of AV or

Art Unit: 3766

VV delay with cardiopulmonary variables for the purpose of optimizing pacing parameters in a pacemaker (Col. 4, lines 61-67; Col. 5, lines 1-7; Col. 6, lines 7-12, 33-64). Tockman further teaches having a cardiologist set the cardiac cycle pacing parameters for the pacemaker, which is considered equivalent to Applicant's use of a boundary conditions table, for the purpose of maintaining safe operating parameters for the patient (Col. 3, lines 62-65). Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to modify the method of Anderson to associate each cardiopulmonary data set with a unique value of AV or VV delay, where the AV and VV delay values are defined in a boundary conditions table, in order to optimize the pacing parameters in a pacemaker for patient health and safety.

Allowable Subject Matter

17. Claims 12 and 13 would be allowable if rewritten to overcome the claim objections set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Conclusion

18. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

- a. Mulligan et al. (US 2005/0027323) shows an implantable medical device with methods for optimizing pacing.
- b. Holstrom et al. (US 6,985,772) shows an implantable medical device with methods for optimizing pacing.
- c. Belalcazar (US 2003/0097158) shows an implantable medical device with methods for optimizing pacing.

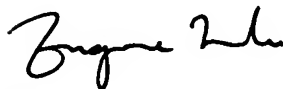
Art Unit: 3766

- d. Mault (US 6,517,496) shows a device for measuring respiratory variables and calculating cardiac output.
- e. Haryadi et al. (US 6,258,038) shows a device for measuring respiratory variables and calculating cardiac output.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eugene T. Wu whose telephone number is (571) 272-3109. The examiner can normally be reached on M-F: 8 AM - 5 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Pezzuto can be reached on (571) 272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



ETW
08/24/2006



Robert Pezzuto
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